

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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UNITED STATES OF AMERICA

v.

ELAN PHARMACEUTICALS, INC.,

Defendant

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Criminal No. 1:10-cr-10431-MBB

**DEFENDANT’S SENTENCING MEMORANDUM**

Defendant Elan Pharmaceuticals, Inc. (“EPI”) respectfully submits this memorandum in support of the proposed Rule 11(c)(1)(C) plea agreement and agreed-upon sentence in this case.

**I. FACTUAL ALLEGATIONS**

EPI does not dispute that it committed the misdemeanor offense to which it is has agreed to plead guilty, nor does it dispute that there is a sufficient factual basis to support this Court’s acceptance of its guilty plea and the imposition of the agreed-upon sentence in this case. EPI acknowledges that between May 2000 and April 28, 2004, it did introduce for delivery into interstate commerce various quantities of a misbranded drug, Zonegran, in violation of Title 21, United States Code, Sections 331(a), 333(a)(1), and 352(f)(1). Specifically, EPI did promote Zonegran for uses that were not included in the Zonegran label that had been approved by the U.S. Food and Drug Administration (“FDA”). EPI does not agree with all of the manner and means asserted by the Government in the Information and its Sentencing Memorandum, but the

Court does not need to resolve any factual disagreements in order to proceed with this plea and sentencing.<sup>1</sup>

## **II. ELAN HAS UNDERGONE A SUBSTANTIAL TRANSFORMATION SINCE 2004 WHEN IT DIVESTED ZONEGRAN**

It has been nearly seven years since Elan divested Zonegran, and the Elan of 2011 is a very different company than the one involved in the conduct at issue. A shift from promotion of pharmaceutical products to research and development related activities, extensive turnover within senior management and the Board of Directors, and enhancements to compliance programs and other controls are just some of the more significant changes at Elan since 2004.

### **A. Shift to World-Class Research and Development**

In 2002, two years after Zonegran was launched, the Company implemented a two-year financial recovery and strategic restructuring plan designed to establish it as a viable research and development enterprise that could offer breakthrough treatments for debilitating neurodegenerative and autoimmune diseases. As part of this plan, Elan divested a number of products, including Zonegran in 2004. In accordance with the terms of the sale of Zonegran, Elan assigned and transferred substantially all of its Zonegran-related assets, including all Zonegran marketing materials and Zonegran books and records. Additionally, Elan's Zonegran sales force was transferred, and Elan ceased all marketing and promotional efforts with respect to Zonegran. At present, the Company does not employ any sales representatives.

Since divesting Zonegran in 2004, Elan's focus has been research, development, and application of groundbreaking therapeutic products for grievous illness. The Company has

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<sup>1</sup> One issue raised by the government that should be addressed is the reference to a Securities and Exchange Commission ("SEC") investigation of Elan Corporation, plc ("Elan"), EPI's corporate parent, in early 2002. *See* Gov't Mem. at 8. In February 2005, the SEC approved a settlement in this matter under which Elan neither admitted nor denied any wrongdoing and paid a \$15 million civil penalty. In connection with the settlement, Elan was not required to restate any of its historical financial results or information.

emerged as a world-leader in developing potential treatments for devastating neurodegenerative and autoimmune diseases including Alzheimer's disease, multiple sclerosis, Crohn's disease, and Parkinson's disease. EPI is currently among the leading biotech or pharmaceutical companies in the world working to develop treatments for Alzheimer's disease, with demonstrated success advancing potential therapies to mid-stage and late-stage clinical development.

The Company's current neuroscience research and development pipeline is comprised of multiple programs, including late-stage clinical trials, designed to affect the accumulation of amyloid plaques and toxic beta amyloid species found in the brains of Alzheimer's disease patients and widely believed to contribute to Alzheimer's disease. Elan also continues to explore cutting-edge compounds that can prevent toxic aggregation of amyloid plaque, as well as programs focused on small molecule inhibitors and compounds that could protect neurons from Alzheimer's disease. In the area of Parkinson's disease research, Elan focuses on developing therapies that disrupt the formation of Lewy bodies, which are considered the hallmark of Parkinson's disease. Elan's efforts have already proven enormously promising during preclinical research, and in the development of animal models of these diseases.

In its efforts to develop potential therapies to combat autoimmune diseases, Elan's core research team pioneered the hypothesis that subsequently informed the development of many treatments for debilitating inflammatory diseases. The Company's current research and development pipeline includes multiple programs designed to prevent or disrupt immune cell invasion and the chronic inflammation-neurodegeneration cycle that leads to permanent disability in patients suffering from advanced autoimmune diseases. Elan's efforts to combat debilitating autoimmune disease have been enormously successful and hold out the continued promise of potential breakthroughs going forward.

**B. Changes to Senior Management and the Board of Directors**

During the course of the strategic restructuring plan, Elan made substantial changes at the senior management level by hiring new individuals in the following positions – Chief Executive Officer, General Counsel, President, Head of Corporate Communications, Head of Investor Relations, Chief Commercial Officer, Controller, Chief Compliance Officer, and the Head of Human Resources.

Today, the Company is committed to developing novel therapies for a range of neurodegenerative and autoimmune diseases and adheres to the highest legal and ethical standards. The Company's Board of Directors has also undergone almost total renewal since the completion of the strategic restructuring plan. The vast majority of the Company's current directors joined the board after 2004.

**C. Enhanced Compliance Efforts**

Elan has made substantial efforts over the past several years to enhance its compliance program, which initially focused on issues relating to quality and manufacturing issues. Upon the appointment of new General Counsel in 2004 and in light of the issuance of the U.S. Department of Health and Human Services' Office of the Inspector General's ("OIG") compliance guidance for pharmaceutical manufacturers in 2003, the Company began to expand the focus of its compliance program and other controls on sales and marketing activities. In March 2010, Elan altered its reporting structure such that the Chief Compliance Officer hired in 2010 now reports directly to Elan's Chief Executive Officer and makes regular reports on compliance activities to the Audit and Finance Committee of Elan's Board of Directors, which oversees compliance activities from a Board perspective. Since the time of the conduct at issue, the Company has demonstrated a substantial commitment to enhancing compliance,

strengthening controls, redirecting the compliance program's focus, and engaging additional resources.

To further enhance Elan's compliance program, the Company, following an extensive executive recruiting search, hired a new Senior Vice President and Chief Compliance Officer with more than eighteen years of compliance and legal experience at Fortune 500 companies and law firms, including other pharmaceutical companies. In addition, Elan bolstered its compliance efforts by hiring in-house counsel with FDA regulatory expertise to support its non-promotional medical field force. Elan also tightened controls around continuing medical education grants and health care professional relationships, and revised and expanded the Company's internal audit functions.

### **III. THE CORPORATE INTEGRITY AGREEMENT COMPLEMENTS THE COMPANY'S EXISTING COMPLIANCE PROGRAM**

In connection with the resolution of this matter, the Company entered into a five-year Corporate Integrity Agreement ("CIA") with OIG. As the Government's Sentencing Memorandum notes, the Company's present focus is on research and development for devastating neurodegenerative and autoimmune disease. *See* Gov't Mem. at 13. The CIA is, therefore, forward-looking, and applies to promotional activities only to the extent that Elan engages in marketing and promotional activities in the future. The CIA requires Elan to notify OIG if it plans to resume promotional or marketing activities in the United States. At that time, OIG and Elan agree to amend the CIA requirements to address new marketing and promotional operations as appropriate.

The CIA incorporates a number of initiatives implemented by the Company, including its compliance program and compliance measures designed to address the Company's U.S. health care operations and compliance with federal health care programs and FDA requirements. The

CIA requires the maintenance of several elements of the Company's existing compliance program, including, but not limited to, a Chief Compliance Officer, Compliance Committee, and Code of Conduct.

Elan would like to add the following clarifying points concerning the requirements of its CIA:

- The Company has engaged PricewaterhouseCoopers ("PWC") to serve as an Independent Review Organization ("IRO") to help the company assess and evaluate its Government Pricing and Contracting Functions, its Medical Affairs and Materials Related Functions, and the funding of educational grants and healthcare related charitable contributions. The Audit Committee of the Board of Directors is not required under the CIA, as the Government implied, to retain a Compliance Expert to conduct a review of the Company's Compliance Program.
- The Company is required under the CIA to send an annual letter to Third Party Personnel outlining the Company's obligations under the CIA and its commitment to compliance. In addition, the IRO, as described above, will review educational grants and healthcare related charitable contributions. However, the CIA does not require doctor notification concerning this resolution or physician payment posting on the Company's website, as the Government's Sentencing Memorandum stated.

### **CONCLUSION**

EPI respectfully requests that the Court accept its Rule 11(c)(1)(C) guilty plea and impose the agreed-upon sentence. The agreed-upon disposition in this case is a component of a global settlement covering the charged conduct that includes multiple settlement agreements involving the federal government, fifty states and the District of Columbia, and the *qui tam*

Relator. This global settlement was negotiated among the numerous parties over the course of nearly two years. On the issue of restitution, EPI agrees that determining issues of loss and causation with respect to third party payors who may have reimbursed for Zonegran purchases over a decade ago would be extraordinarily complicated, if not impossible. It should also be noted that there are no existing personal injury claims against EPI or Elan in connection to Zonegran. EPI concurs with the Government that the global resolution reached in this case appropriately takes into consideration the nature and seriousness of the offense, promotes respect for the law, and that the fine imposed and the CIA provide adequate specific and general deterrence.

Respectfully submitted,

Elan Pharmaceuticals, Inc.,

By its attorneys,

/s/ Joshua S. Levy  
Joshua S. Levy (BBO#563017)  
joshua.levy@ropesgray.com  
Matthew B. Arnould (BBO#675457)  
matthew.arnould@ropesgray.com  
ROPES & GRAY LLP  
Prudential Tower  
800 Boylston Street  
Boston, MA 02199-3600  
Telephone: (617) 951-7000  
Fax: (617) 951-7050

Dated: January 28, 2011

**CERTIFICATE OF SERVICE**

I hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) on January 28, 2011.

/s/ Matthew B. Arnould  
Matthew B. Arnould